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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018
321	7590	05/18/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/803,819	Applicant(s) SYVERSON ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5,12,13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-23-06; 1-27-06, 8-18-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 2-27-06 is acknowledged.

Claims 1-60 are present in the case. Claims 1-4, 6-11 and 14-25 are considered for examination. Claims 5, 12, 13 and 26-60 are withdrawn from consideration.

Response to Arguments

Response to Arguments

Applicants' arguments filed 2-27-06 have been considered but not found persuasive. The following rejections of record have been maintained:

Claim Rejections - 35 USC § 103

1. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,470,978 to Stolar in view of US 6,416,779 to D'Augustine.

A complete rejection under this section can be found in the previous action.

RESPONSE: Applicants argue that Stolar teaches an antibacterial composition comprising phenoxyethanol (reads on the claimed compounds), trimethoprim and an antibacterial sulfa drug, to treat bacterial infections. It is argued that Stolar does not disclose phenoxyethanol as an antibacterial agent and only teaches the compound in a group of three compounds. In response to this, Stolar clearly suggests including a synergistically effective amount of phenoxyethanol in the total "antibacterial composition" (col. 1, lines 40-55), thus implying antibacterial property of phenoxyethanol. Applicants argue that Stolar teaches oral administration and therefore one would not be motivated to use phenoxyethanol in the non-absorbent devices of

Art Unit: 1615

D'Augustine. In response to this, Stolar not only teaches tablets but also teaches solutions, suppositories etc., suggesting other routes of administration and therefore the argument that an oral composition cannot be combined with non-absorbent device such as tampons is moot.

It is argued that Stolar fails to teach non-absorbent substrates of the instant claims, for insertion in to vagina. However, the instant rejection is made over a combination of references and the teaching of D'Augustine has been relied upon for the claimed non-absorbent materials. Applicants argue that the combination of the teachings of D'Augustine i.e., the use of vaginal devices and antibacterial, antifungal or antiviral composition for treating vaginal infections, does not meet the requirements for establishing prima facie obviousness, without the blue print of applicants' disclosure. Applicants argue that the motivation to combine the above references is not convincing as to why one skilled in the art would particularly pick phenoxyethanol of Stolar from a mixture of three compounds, when D'Augustine describes numerous suitable antibacterial compositions to use with their non-absorbent devices. Applicants' arguments are not persuasive because Stolar suggests a synergistic increase in the antibacterial activity by the addition of phenoxyethanol with other two compounds. On the other hand D'Augustine teaches antibacterial compounds but does not teach the highly synergistic effect in treating bacterial infection, which is suggested by Stolar. Further, instant comprising language does not exclude the presence of the other antibacterial compounds of either Stolar or D'Augustine. With respect to the argument the exoprotein inhibiting effect of phenoxyethanol, instant claims do not exclude killing

Art Unit: 1615

of the bacteria along with inhibiting protein nor do they recite that "good" bacteria is not killed. Further, it is to be noted that the while the ultimate effect of an antibacterial agent is killing the bacteria, such an effect includes inhibiting proteins, including exoprotein. Thus, the antibacterial teaching of Stolar is inclusive of inhibiting exoprotein.

Examiner has withdrawn the rejection of claims over US 5,728,690 to Chen and D'Augustine in view of Stolar and accordingly the arguments pertaining to this rejection are moot.

In response to applicants' arguments regarding the double patenting rejection, examiner notes that due to a typographical error, the previous action stated the double patenting rejection over US 6,281,999. Accordingly, the previous double patenting rejection has been withdrawn and a new rejection is issued as follows:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1615

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-11 and 14-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent 6,821,999 in view of any one of US 5,612,045 ('045), US 5,685,872 ('872) or US 5,618,554 ('554). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims directed to a method of inhibiting the production of TSST-1 from Gram positive bacteria located in and around the vagina by exposing the vaginal bacteria to a vaginal cleansing formulation comprising thiomolactone and a second active ingredient comprising the general formula (II) that includes the first active compounds of the instant claims. Thus, the patented claims employ the compounds of the instant claims for the same purpose i.e., exoprotein inhibition, as that claimed. While the patented claims fails to recite the claimed non-absorbent device, each of '554, '045 or '872 teach the compounds of patented claim 2 as exoprotein inhibitors coated on absorbent or non-absorbent intra-vaginal devices such as catamenial tampons. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to use the compounds of formula II alone or in combination with exoprotein inhibiting compounds such as those recited in claim 2 of the patent together with non-absorbent vaginal devices for inhibiting exoprotein production by Gram positive bacteria in the vaginal area because the patented claims teach these compounds as effective for the same purpose and further all of '554, '045 and '872 teach applying the exoprotein inhibitor compounds on

Art Unit: 1615

absorbent articles as well as non-absorbent articles that hold absorbent articles so as to successfully deliver the compounds to the vaginal area. Further, optimizing the amounts of each of the active agents so as to achieve complete inhibition of exoprotein would have been within the scope of skilled artisan.

Examiner notes that previous action inadvertently rejected claims 11-13, when claims 14-25 have been elected as a subs-species. Accordingly, the rejection of claims 11-13 has been withdrawn and the following new rejection has been applied:

3. Claims 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,470,978 to Stolar in view of US 6,416,779 to D'Augustine and US 5,612,045 ('045).

Stolar teaches a composition comprising phenoxyethanol, trimethoprim and sulfa drugs for their antimicrobial effect (col. 1). Stolar teaches that addition of phenoxyethanol increases the synergistic effect of other antimicrobial compounds and also suggests preparing the compositions as tablets, suspensions, suppositories etc., but fails to teach the claimed devices.

D'Augustine teaches a method of treating vaginal infections by administering the antibacterial, antimicrobial compounds etc., on a vaginal device such as absorbent or non-absorbent devices including tampons, rings etc (col. 2, col. 3, and col. 7, brief description of figures).

Art Unit: 1615

'045 teach absorbent articles and non-absorbent articles such as catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus* (abstract, col. 3, lines 40-60). The compounds of '045 comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). '045 teach including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5) but fail to teach the compounds of instant claim 1.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Stolar together with ether compounds in the articles of '045 because D' Augustine suggests using non-absorbent devices for administering antimicrobial compounds to treat vaginal infections and '045 also teach administering compounds effective to treat vaginal infections by including them on the absorbent or non-absorbent devices such as tampons. Accordingly, a skilled artisan would have expected to achieve an effective treatment of vaginal infections with phenoxyethanol of Stolar and also successfully inhibit exoprotein production by the bacterial population of vagina.

No claim allowed.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 12, 2006